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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,770	07/13/2001	Bettina Moeckel	203979US0X	1467

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EXAMINER
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ART UNIT	PAPER NUMBER
1652	4

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/903,770	Moeckel et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- *The MAILING DATE f this communication appears n the cover sheet with th correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above, claim(s) *20-36 and 39* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-19, 37, and 38* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-19, 37, and 38, in Paper No. 8 is acknowledged. The traversal is on the grounds that Groups VII-IX which depend from the claim 1 should not be separated from Group I. This is not found persuasive because the methods of Groups VII-IX do not require the product of Group I for their practice and the polynucleotide of Group I can be used in a materially different process of using the product such as using the polynucleotide in a recombinant process for producing a polypeptide.

The requirement is still deemed proper and is therefore made FINAL. Claims 20-36 and 39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Claims 1-19, 37, and 38 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-19, 37, and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to all polynucleotides that are at least 70%, 80%, or 90% identical to the polynucleotide of SEQ ID NO: 1 or a polynucleotide which encodes SEQ ID NO: 2. The specification only discloses SEQ ID NO: 1 and SEQ ID NO: 2 as representative species of the claimed invention. However, the specification does not provide a written description of any structure to function or activity relationship in the claimed polynucleotide. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a

skilled artisan would recognize Applicants were in possession of the claimed invention.

5. Claims 1-19, 37, and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompasses any polynucleotide which is at least 70%, 80%, or 90% identical to SEQ ID NO: 1. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of any polynucleotide which is at least 70%, 80%, or 90% identical to SEQ ID NO: 1 is lacking. Thus, searching for the biological function, biological activity, or utility of said polynucleotides is well outside the realm of routine experimentation and predictability in the art of success is extremely low. Furthermore, searching for the specific nucleotides to add, delete, substitute, or combinations thereof to SEQ ID NO: 1 is well outside the realm of routine experimentation.

The amount of experimentation to determine the biological function, biological activity, or utility of said polynucleotides or the specific nucleotides to add, delete, substitute, or combinations thereof to SEQ ID NO: 1 is enormous. Such experimentation entails screening a vast number of organisms for an organism that contains a polynucleotide which is at least 70%, 80%, or 90% identical to SEQ ID NO: 1 and determining the biological function, biological activity, or utility of the polynucleotide. Furthermore, experimentation also entails selecting specific nucleotides in SEQ ID NO: 1 to add, delete, substitute, or combinations thereof to make a polynucleotide which is at least 70%, 80%, or 90% identical to SEQ ID NO: 1 and determining the biological function, biological activity, or utility of the polynucleotide.

Since routine experimentation in the art does not include screening vast numbers of organisms for an organism that contains a polynucleotide which is at least 70%, 80%, or 90% identical to SEQ ID NO: 1 and determining the biological function, biological activity, or utility of the polynucleotide or selecting specific nucleotides in SEQ ID NO: 1 to add, delete, substitute, or combinations thereof to make a polynucleotide which is at least 70%, 80%, or 90% identical to SEQ ID NO: 1 and determining the biological function, biological activity, or utility of the polynucleotide, where the expectation of obtaining a desired biological function, biological activity, or utility is unpredictable, the Examiner finds that one skilled in the art would require

additional guidance, such as information regarding the structure and function relationship of the claimed polynucleotides. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-19, 37, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that SEQ ID NO: 2 is an amino acid sequence, and claim 3 recites that SEQ ID NO: 1 is a nucleotide sequence. However, the "Sequence Listing" states that SEQ ID NO: 2 is a nucleotide sequence and SEQ ID NO: 1 is an amino acid. Claims 1 and 3 are indefinite because the specific amino acid sequence and nucleotide sequence claimed is not known. Claims 2-19, 37, and 38 which depend from claim 1 or claim 3 are also rejected because they do not correct the defect of claim 1 or claim 3.

In claims 2 and 9, the phrase "LysR1 transcriptional regutory activity" renders the claim indefinite and ambiguous because the specific activity which is regulated by the claimed polypeptide is not known.

Claims 5-7 are indefinite because the specific nucleotides to change in the reference polynucleotide to make the claimed polynucleotide which is at least 70%, 80%, or 90% identical to the reference polynucleotide is not known and not defined in the specification.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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